IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Christopher McDowell			
Serial No.	:	09/960,020	Art Unit	:	3728
Filed	:	September 21, 2001	Examiner	:	J. G. Pickett
Title	**:**	**Tray for Surgical Fasteners**			

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June 12, 2006
(Date of Signature)

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF

Dear Sir:

This Appeal Brief is filed in response to the Notice of Appeal, which was mailed by Applicant to the U.S. Patent & Trademark Office on December 12, 2005.

Real Party In Interest:

The real party in interest for this patent application is Codman & Shurtleff, Inc., 325 Paramount Drive, Raynham 02767.

Related Appeals and Interferences:

There are no related appeals or interferences known to Appellant, the Appellant's legal representative, or the Assignee that will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

Status of Claims:

Claims 2, 4, 5, 7, 10 and 13-15 have been cancelled.

Claims 1, 3, 6, 8, 9, 11, 12 and 16 are pending, have been finally rejected, and are hereby appealed.

Status of Amendments:

No amendments have been filed after the final rejection of September 12, 2005.

Summary of Invention:

In general, the invention relates to a tray 88 that holds one or more surgical fasteners 66. See, for example, the description of the invention at page 5, line 31 through page 6, line 10 and Figures 7-10 of the specification. The tray 88 has a base 90, which has at least one well 94 therein, one of the surgical fasteners 66 within the base 90 and a film 96 over the base 90 and the well 94. The film 96 at the location of the well 94 is treated to make it easier for an instrument to penetrate the film and access the well to remove the fastener. The treatment can comprise providing a weakness in the film such as scoring. Preferably, the well and the surgical fastener are sterile. The film 96 thus holds the fasteners 66 in the wells 94 and maintains the sterility. Independent claims 1 and 8 define the following different inventions:

Claim 1 recites an invention directed to a tray 88 for holding a plurality of surgical fasteners 66. Tray 88 comprises a base 90 having a plurality of wells 94 therein. At least two of the surgical fasteners 66 are disposed within respective ones of the plurality of wells 94. A film 96 is disposed over the base 90 and the plurality of wells 94. A weakness is formed in the film 96 over the plurality of wells 94 to more easily allow an instrument to penetrate the film 96 and enter one of the wells 94. Each of the wells 94 and the surgical fasteners 66 within each well are maintained in a sterile environment regardless if any of the other wells have been opened.

Claim 8 recites an invention that relates to a method of holding surgical fasteners 66. A tray 88 is provided, which has a base 90. Base 90 has a plurality of wells 94 disposed therein. At least one of the surgical fasteners 66 is provided in one of the wells 94. Wells 94 are covered with a film 96. Film 96 over the wells is modified to ease the ability of an instrument to penetrate the wells 94. The wells and surgical fasteners disposed therein are sterilized. The film is penetrated to access one of the surgical fasteners in one of the wells while maintaining the sterile environment in the remaining wells.

Issues:

Whether the final rejection of claims 1, 3, 6, 8, 9, 11, 12 and 16 under 35 USC §103(a) as being unpatentable over U.S. Patent No. 5,968,044 to Nicholson et al. (hereinafter referred to as Nicholson) in view of U.S. Patent No. 6,098,802 to Asa et al (hereinafter referred to as Asa) and still further in view of U.S. Patent No. 5,873,462 to Nguyen et al (hereinafter referred to as Nguyen) should be reversed.

Grouping of Claims:

Claims 1, 3, 6, 8, 9, 11, 12 and 16 stand or fall together.

Argument:

Rejection of claims 1, 3, 6, 8, 9, 11, 12 and 16 under 35 USC §103(a)

The Examiner maintains that Nicholson discloses a surgical fastener in the form of a disposable portion 100. The Examiner states that Nicholson suggests placing the fastener in a sterile tray. But the Examiner admits that Nicholson does not even attempt to teach or suggest the structure of this tray.

The Examiner is relying on Asa and Nguyen for the alleged teaching of a tray for the sterile storage of a disposable portion. The Examiner further relies on Asa for the alleged teaching of the wells in the tray being isolated to prevent cross contamination. The Examiner also further relies on Nguyen for the alleged teaching of scoring a film to allow for controlled breaking of the film. The Examiner concludes that it would have been obvious to one of

ordinary skill in the art to provide Nicholson's nondescript tray with isolated wells based on the teachings of Asa to prevent cross-contamination of the fasteners and with a film on top of the tray with a score on the film over each well based on the teachings of Nguyen.

Independent claims 1 and 8 of the present invention require that a film be placed over the wells such that accessing one of the surgical fasteners in one of the wells can be achieved while maintaining the sterile environment in the remaining wells, regardless if any of the other wells have been opened. In other words, should the film be penetrated to access one of the surgical fasteners in one of the wells, the sterile environment in the remaining wells is maintained.

Nicholson discloses a bone fastener and the entire disclosure is directed to structural details of the bone fastener. Nicholson states that his invention also includes a surgical fastener kit, which includes an expandable member that has an axial channel and an outer surface for engaging an inner surface of the bone opening. The kit also includes an element for insertion into the axial channel. This element has a projecting surface for engaging the inner surface of the axial channel. The kit also includes a holder for engaging with the expandable member. The holder is capable of maintaining the expandable member in position with the bone opening. The kit may also include a grasper for the suture, a drill and a retrieval device. Nicholson states that the kit is preferably encased in a sterile tray or other receptacle for use by an operator at a site. Thus, it is abundantly clear that Nicholson's sterile tray is intended to hold an expandable member, an element for insertion into the axial channel, and maybe even a grasper, a drill and a retrieval device. In fact, there is no mention whatsoever of the tray holding the bone fasteners. Therefore, there is no need to provide a plurality of wells as all of these devices are going to be used during the surgical operation. Thus, one of ordinary skill in the art would not have been motivated to modify Nicholson's tray so that it has a plurality of wells. Additionally, there would be no need to provide a weakness in the film over each well.

Thus, the combination of Nicholson, Asa and Nguyen fails to teach or suggest the present invention as exemplified by amended independent claims 1 and 8, which require that the sterile environment in the remaining wells be maintained regardless of whether any of the other wells have been opened.

In response to these arguments, the Examiner states on pages 4-5 of the Final Rejection that "[W]hile Nicholson does disclose a preferred embodiment wherein the tray

holds the fasteners in addition to other components in the assembly, this does not detract from the fact that disposable cartridges are also disclosed (see for example, Col. 16, lines 2-10)." Applicant has reviewed Column 16, lines 2-10 of Nicholson and fail to find language that suggests that refutes Applicant's arguments above. Nicholson states at column 16, lines 7-10, that "[T]he fastener assembly can include a disposable cartridge, the cartridge containing the expandable member, insertion element, holding means, and means for attaching the disposable cartridge to the apparatus."

Thus, it is still abundantly clear that Nicholson's disposable cartridge, which isn't expressly disclosed as being sterile, is intended to hold an expandable member, an insertion element, holding means, and means for attaching the disposable cartridge to the apparatus. Once again, there is no mention whatsoever of the cartridge holding the bone fasteners. Therefore, there is no need to provide a plurality of wells as all of these devices are going to be used during the surgical operation. Thus, one of ordinary skill in the art would not have been motivated to modify Nicholson's disposable cartridge so that it has a plurality of wells. Additionally, there would be no need to provide a weakness in the film over each well.

Thus, the combination of Nicholson, Asa and Nguyen fails to teach or suggest the present invention as exemplified by amended independent claims 1 and 8, which require that the sterile environment in the remaining wells be maintained regardless of whether any of the other wells have been opened.

Conclusion:

For the reasons discussed above, Appellants maintain that the Examiner's final rejection of claims 1, 3, 6, 8, 9, 11, 12 and 16 under 35 USC §103(a) should be reversed.

Respectfully submitted,

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APPENDIX

1. (Amended) A tray for holding a plurality of surgical fasteners, the tray comprising a base having a plurality of wells therein, at least two of the surgical fasteners being disposed within respective ones of the plurality of wells; and

a film over the base and the plurality of wells, a weakness in the film over the plurality of wells whereby to more easily allow an instrument to penetrate the film and enter one of the wells;

wherein each of the wells and the surgical fasteners within each well are maintained in a sterile environment regardless if any of the other wells have been opened.

2. (Canceled)

3. (Amended) A tray according to claim 1 wherein the weakness comprises scoring of the film.

4. (Canceled)

5. (Canceled)

6. (Amended) A tray according to claim 1 and further comprising ingress means on the film over the plurality of wells to allow an instrument to penetrate the film and enter one of the wells.

7. (Canceled)

8. (Amended) A method of holding surgical fasteners comprising the steps of:

providing a tray having a base with a plurality of wells therein;

providing one of the surgical fasteners in one of the wells;

covering the wells with a film;

modifying the film over the wells to ease the ability of an instrument to penetrate the wells;

sterilizing the wells and surgical fasteners disposed therein; and

penetrating the film to access one of the surgical fasteners in one of the wells while maintaining the sterile environment in the remaining wells.

9. (Original) A method according to claim 8 and further comprising the steps of penetrating the film with an instrument and removing the fastener from the well with the instrument.

10. (Canceled)

11. (Amended) A method according to claim 8 wherein the step of modifying the film over the well to ease the ability of the instrument to penetrate the well comprises providing a weakness in the film.

12. (Original) A method according to claim 11 wherein the weakness comprises scoring the film.

13. (Canceled)

14. (Canceled)

15. (Canceled)

16. (Original) A method according to claim 9 wherein the instrument is an applier for applying the surgical fastener.